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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,179	02/16/2001	Veronique Chevalier	202443US0	3089

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OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER

WILLIS, MICHAEL A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,179

Applicant(s)

CHEVALIER ET AL.

Examiner

Michael A. Willis

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment of 16 April 2002 is entered. Claims 1, 4-7, 9, 10, 12, 15-18, 20, and 21 are amended. Claim 23 is added. Claims 1-23 are pending. Any previous rejections that are not restated in this Office Action are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The Applicant's response to the rejection of claims 1-22 made by the Examiner under 35 U.S.C. 112, second paragraph, and to the objection to the specification fully meets the deficiencies encompassed by said rejection and objection.

Therefore, said rejection and objection are hereby withdrawn.

Response to Arguments

The rejection of claims 1-3, 8, 12-14, and 19 under 35 USC 102(b) is withdrawn. Applicant argues that the specific combination of N-cholesteryloxycarbonyl-4-p-aminophenol and hydroquinone or a hydroquinone derivative is not disclosed. Presumably, such a combination would require picking and choosing from a long list of possible combinations, and therefore does not meet the requirements for anticipation. Applicant's argument is persuasive.

Claims 1-22 are rejected under 35 USC 103(a) as being unpatentable over Philippe et al (WO 99/10318) for reasons as stated previously. Most notably, the

reference teaches that aminophenol derivatives, when combined with other depigmenting agents such as hydroquinone, allow the hydroquinone to be used at doses that are less toxic to the skin.

Applicant argues that the data presented in Examples 1 and 2 of the present application obviate the rejection. Applicant argues that the Examples show unexpected results such as superior skin/hair lightening or depigmenting properties for the hydroquinone plus N-cholesteryloxycarbonyl-4-p-aminophenol composition as compared to the hydroquinone plus N-ethoxycarbonyl-4-p-aminophenol composition.

The comparison of Examples 1 and 2 is not convincing, as the concentrations of the aminophenol components are so different as to prevent a reasonable comparison between the two examples. In Example 1, the claimed species of aminophenol is used at a concentration that exhibits no direct inhibition of tyrosinase. In Example 2, the comparative species of aminophenol is used at a concentration that exhibits a 25% direct inhibition of tyrosinase. A small improvement in the inhibitory effect of hydroquinone is shown by the addition of the claimed aminophenol in Example 1, in agreement with the prior art teaching that the combination allows the hydroquinone to be used at doses that are less toxic to the skin. Example 2 shows roughly the same amount of inhibition of tyrosinase as Example 1, but this amount of inhibition is less than the theoretical inhibition calculated due to a much higher concentration of aminophenol. However, as stated previously, the concentrations of the aminophenols in the Examples are so different as to prevent a direct comparison of the results, and

there are not enough data points to extrapolate the results of tests where similar inhibitory concentrations of aminophenols are used. Furthermore, the examples are in vitro tests with a fungal tyrosinase and are not commensurate in scope to arguments with respect to superior skin/hair lightening or depigmenting properties in vivo. Therefore, the rejection is maintained.

The following new grounds of rejection are made:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/284,490. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to combinations of aminophenol derivatives such as N-cholesteryloxycarbonyl-4-p-aminophenol in combination with other depigmenting agents such as hydroquinone.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on alternate Mon. and Tues. to Fri. from 9am-6:30pm.

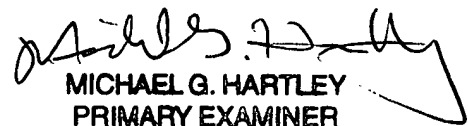
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis
Examiner
Art Unit 1617

June 27, 2002



MICHAEL G. HARTLEY
PRIMARY EXAMINER